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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,712	01/23/2004	Miles B. Brennan	11320/33	9189

7590 11/15/2005

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/764,712	Applicant(s) BRENNAN ET AL.	
	Examiner Jon Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment filed 1/23/2004 is acknowledged and has been entered. Claims 1-9 have been cancelled. Claims 21-23 have been added. Claims 10-23 are currently pending in the application and are addressed herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 11, drawn to a method comprising administering an antagonist of MSH biological activity to a mammal wherein the antagonist is a fragment of MSH, or a homolog of MSH, or a fusion protein comprising the fragment or homolog, classified in class 514, subclass 2, for example.
- II. Claim 11, drawn to a method comprising administering an antagonist of MSH biological activity to a mammal wherein the antagonist is a peptide mimetic of MSH or a fusion protein comprising said peptide mimetic, classified in class 514, subclass 2, for example.
- III. Claim 11, drawn to a method comprising administering an antagonist of MSH biological activity to a mammal wherein the antagonist is a non-peptide mimetic or a fusion protein comprising said non-peptide mimetic, classified in class 514, subclass 1, for example.
- IV. Claim 12, drawn to a method comprising administering an antagonist of MSH biological activity to a mammal wherein the antagonist is a soluble MSH receptor, classified in class 514, subclass 2, for example.

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- V. Claim 13, drawn to a method comprising administering an antagonist of MSH biological activity to a mammal wherein the antagonist is an antibody that selectively binds to MSH, classified in class 424, subclass 130.1.
- VI. Claim 14, drawn to a method comprising administering an antagonist of MSH biological activity to a mammal wherein the antagonist is that selectively binds to MSH receptor, classified in class 424, subclass 130.1.

NOTE: Claim 10 contains an improper Markush Group because it includes (1) a fragment or homolog of MSH, (2), a MSH peptide mimetic, and (3) an MSH non-peptide mimetic. As set forth in *In re Harnisch* (631F.2d 716 206 USPQ 300 (CCPA 1980)), see MPEP 803.02, unity of invention exists for all species in a Markush group if the species (1) have a common utility, **AND** (2) share a substantial structural feature disclosed as being essential to that utility (emphasis added). In the instant case, the species of the Markush group have a common utility, but they do not share a substantial structural feature disclosed as essential to that utility. Specifically, the indicated antagonists are structurally different and do not share a substantial structural feature disclosed as being essential to that utility. Therefore, indicated antagonists have been separated into patentably distinct groups.

Claims 10 and 15-23 link(s) the inventions of Groups I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s)

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are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Specifically, each of the indicated Inventions comprises the use of a structurally and functionally distinct antagonist. Inventions I-III encompass an improper Markush Group of antagonists, as indicated above. Furthermore, the antagonists of Inventions I-III are structurally different because a MSH fragment/homolog would have a different amino acid sequence than a MSH peptide mimetic. Furthermore, the non-peptide mimetic is not comprised of amino acids as are all of the other antagonists. Additionally, a soluble MSH receptor fragment would have a different amino acid sequence than any of the other peptide antagonists. The antibodies of Inventions V and VI would be structurally distinct from the other peptide antagonists as they are antibodies. Furthermore, the antibody of Invention V is structurally and functionally distinct from the antibody of Invention VI because the antibody

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of V selectively binds to MSH, while the antibody of VI selectively binds to an MSH receptor.

Therefore, the Inventions are unrelated.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each Group is different (i.e., the searches are not co-extensive), restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

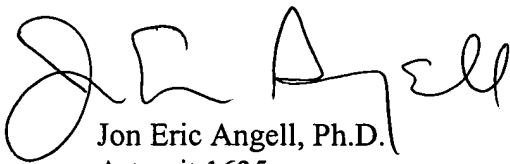
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Eric Angell, Ph.D.
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